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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,783	04/21/2005	Hans Schreier	05/063	6308

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GUDRUN E. HUCKETT DRAUDT
SCHUBERTSTR. 15A
WUPPERTAL, 42289
GERMANY

EXAMINER	
LAM, ANN Y	
ART UNIT	PAPER NUMBER
1641	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,783	SCHREIER ET AL.	
	Examiner	Art Unit	
	ANN Y. LAM	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Colman et al., 5,665,065.

Colman et al. teach a medication infusion device comprising a compact programmable medication infusion pump adapted to receive and support a syringe carrying a prescribed medication such as insulin. The pump further includes a sensor or meter for detecting or receiving a current patient parameter, such as a blood glucose reading. The parameter sensor or meter provides a data input to the pump controller for altering the medication delivery protocol in an appropriate manner. In accordance with the invention, the altered protocol can be automatically implemented, but may in the alternative be recommended to the patient by means of the visual display for convenient acceptance or rejection by manipulation of one or more of the control buttons, or otherwise overridden entirely by the patient in favor of a different or modified delivery protocol. See column 2, lines 46-64.

Colman et al. further teach that in an alternative embodiment, the medication infusion device comprises a manually operated syringe-type implement, such as a

medication delivery pen. The delivery pen includes a manually adjustable dial or the like for retracting a syringe plunger through a predetermined stroke, in association with a visual display which indicates the medication dosage to be delivered. The delivery pen includes a controller which receives a patient parameter input from a sensor or meter, such as a current blood glucose reading. The controller responds to the data input representing the patient parameter to recommend a dispensing protocol which can be accepted or modified by the patient. See column 2, line 65 – col. 3, line 11. A glucose sensor or meter 16' such as a built-in sensor for receiving and reading a glucose test strip, provides a data input to the delivery pen 10'. An internal controller responds to the data input to provide a recommended medication dispensing protocol via the display 26'. The patient may operate the dial 42 and plunger 44 to deliver the recommended dosage, or a modified
dosage in accordance with current patient activity and requirements. See column 5, lines 15-40.

Moreover, Colman et al. disclose that in a further alternative form of the invention, the sensor or meter may be provided for substantially continuous in vivo patient monitoring, such as an implanted or subcutaneous glucose sensor. The in vivo sensor is associated with a radio telemetry transmitter for sending a patient parameter signal to the infusion device which includes a receiver. The controller of the infusion device responds to the telemetered data input to recommend a medication delivery protocol which can be followed or modified by the patient.
(col. 3, line 12-20).

Colman et al. further describes that a pump controller 24 responds to a data input from the glucose sensor or meter 16, in addition to manually inputted instructions by means of the buttons 22. The glucose sensor or meter 16 is conveniently mounted directly onto the pump housing 18 in a readily accessible position, depending upon the type of glucose sensor or meter used. The sensor or meter 16 may be coupled in a suitable manner to an implantable or subcutaneous glucose sensor of the type described, for example, in U.S. Pat. No. 4,671,288. Data input is provided to the controller 24 so that pump operation may be regulated in accordance with controller programming and in response to a current patient condition parameter such as blood glucose level. See column 4, lines 11-30. The sensor 16" is associated with a transmitter 46 used to send an appropriate glucose data signal via radio telemetry or infrared transmission to an appropriate receiver provided as part of the medication infusion device 10'. The radio telemetered glucose data signal is inputted to the pump 10", which then operates a pump controller. See column 5, lines 41-60)

As to claims 8 and 11-13, the infusion device is equivalent to the claimed dosimeter comprising a chip (e.g., a delivery pen) and dispensing means (e.g., plunger, or pump). The glucose sensor is equivalent to the claimed diagnostic indicator system. As discussed above, the infusion device receives data from the sensor to control the dosage.

As to claim 10, it is understood that the telemetered glucose data signal provides electronic information to the diagnostic indicator system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colman et al., 5,665,065, in view of Gough, 4,671,288.

Colman et al. has been discussed above. However, Colman et al. do not disclose details about the diagnostic indicator system. For example, while Colman et al. disclose that the infusion device has a meter for receiving and reading a glucose test strip, for providing data to the infusion device (column 5, lines 15-40), there is no disclosure that the strip is impregnated with a chemical or biological indicator substance.

Colman et al. however do cite 4,671,288, patented to Gough, as an example of a glucose sensor.

Gough teaches an electrochemical cell sensor for detecting glucose (col. 1, lines 12-18) comprising a housing 10 with two oxygen sensors 16 and 18. An oxidase enzyme is situated physically near the surface of the sensor 18 by embedding it in a porous gel 20 that surrounds the sensor. The second oxygen sensor 16 is utilized to

monitor the oxygen concentration of the environment and, hence, is devoid of enzyme. See column 2, line 55 to col. 3, line 12.

While Colman et al. disclose a glucose sensing device but do not disclose that the device is impregnated with a chemical or biological indicator substance, such is well known in the art for detecting glucose, as shown by Gough. Moreover, it would have been obvious to the skilled artisan at the time of the invention to provide the Gough glucose sensor as the particular type of glucose sensor in the Colman et al. system, particularly because Colman et al. specifically lists the Gough patent as a type of glucose sensor that can be used in the system.

Response to Arguments

Applicant's arguments with respect to claims 8-13 have been considered but are moot in view of the new ground(s) of rejection as necessitated by the amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641